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Total Number of Pages in This Submission

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Application Number

10/755,849

Filing Date

January 12, 2004

First Named Inventor

Walter M. Bain

Art Unit

3653

Examiner Name

Jeffrey A. Shapiro

Attorney Docket Number

1311.DDN.CN

**ENCLOSURES (Check all that apply)**

Fee Transmittal Form



Fee Attached



Amendment/Reply



After Final



Affidavits/declaration(s)



Extension of Time Request



Express Abandonment Request



Information Disclosure Statement



Certified Copy of Priority Document(s)

Reply to Missing Parts/  
Incomplete ApplicationReply to Missing Parts  
under 37 CFR 1.52 or 1.53

Drawing(s)



Licensing-related Papers



Petition

Petition to Convert to a  
Provisional ApplicationPower of Attorney, Revocation  
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After Allowance Communication to TC

Appeal Communication to Board  
of Appeals and InterferencesAppeal Communication to TC  
(Appeal Notice, Brief, Reply Brief)

Proprietary Information



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Other Enclosure(s) (please identify  
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July 21, 2006

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# FEE TRANSMITTAL

## For FY 2006

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 250.00

### Complete if Known

Application Number	10/755,849
Filing Date	January 12, 2004
First Named Inventor	Walter M. Bain
Examiner Name	Jeffrey A. Shapiro
Art Unit	3653
Attorney Docket No.	1311.DDN.CN

### METHOD OF PAYMENT (check all that apply)

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#### 1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

#### 2. EXCESS CLAIM FEES

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180
<b>Total Claims</b>		
- 20 or HP = _____ x _____ = _____		
HP = highest number of total claims paid for, if greater than 20.		
<b>Indep. Claims</b>		
- 3 or HP = _____ x _____ = _____		
HP = highest number of independent claims paid for, if greater than 3.		

#### 3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
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#### 4. OTHER FEE(S)

Non-English Specification, \$130 fee (no small entity discount)	
Other (e.g., late filing surcharge): <u>Appeal Brief Fee</u>	250

SUBMITTED BY		
Signature <u>Randall B. Bateman</u>	Registration No. (Attorney/Agent) <u>37,774</u>	Telephone (801) 533-0320
Name (Print/Type) <u>Randall B. Bateman</u>	Date <u>July 21, 2006</u>	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: Walter M. Bain  
Serial Number: 10/755,849  
Filed: January 12, 2004  
Art Unit: 3653  
Examiner: Jeffrey A. Shapiro  
For: Automated Prescription  
Dispensing System and  
Method of Use  
Attorney Docket: 1311.DDN.CN

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Randall B. Bateman

APPEAL BRIEF

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07/25/2006 MBLANCO 00000006 10755849

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This brief is submitted in the format of 37 C.F.R. § 41.37(c):

07/25/2006 MBLANCO 00000006 10755849

(1) REAL PARTY IN INTEREST

The real party in interest in the present pending appeal is Distributed Delivery Networks, Inc., the assignee of the above-referenced application.

(2) RELATED APPEALS AND INTERFERENCES

There are no related appeals, interferences, or litigation.

(3) STATUS OF THE CLAIMS

Claims 60-112 are pending. Claims 1-59 have been canceled.

Claims 60-112 stand rejected.

(4) STATUS OF AMENDMENTS

The last amendment was filed on April 25, 2006, and was responsive to the Final Office Action of March 6, 2006, and the Advisory Action of April 11, 2006. The April 25, 2006 Amendment was entered for purposes of appeal pursuant to the Advisory Action of May 18, 2006.

(5) SUMMARY OF THE INVENTION AND OF CLAIMED SUBJECT MATTER

The invention defined by the claims in the pending appeal relates to a method of dispensing prescription medication. While it is important for patients to be able to obtain their prescriptions, the hours of operation of the pharmacy provides a limitation for many people. Likewise, some pharmacies are so busy that customers must wait for prescriptions to be filled,

and other pharmacies have difficulty with staffing because of the shortage of pharmacists. (2:12-3:16)

The claims of the present invention describe methods which help alleviate these concerns by placing filled prescriptions (i.e. containers of medication labeled with the patient's name and other relevant information such as frequency and dosing) in an automated dispensing unit. The filled prescriptions can be placed in the dispensing unit at times convenient to the pharmacist. The location of each filled prescription is recorded so that the prescription can be retrieved when needed. (6:10-8:18)

The filled prescription(s) for a particular patient can be retrieved from the dispensing unit by the patient whenever it is convenient. A number of security procedures are provided to prevent a patient from receiving the wrong prescription. Additionally, the invention allows the insurance company or other third party payer to be billed when the medication is actually dispensed to the patient, rather than billed when the prescription is filled, thereby eliminating the need for charge backs caused by patients who fail to pick up their prescriptions. (6:10-8:18)

The elements of the independent claims are hereby presented with reference numerals corresponding to the drawings and with reference to the specification so as to allow for easier understanding of the claimed invention.

60. A method for dispensing medication comprising:

filling a prescription by placing information unique to a single patient on a container of medication (29:13-17; 41:10-12);

utilizing an automated medication dispenser (12:4-11; FIG. 1, 4; 21:16-22:7; FIG. 2, 112), the dispenser being located in a pharmacy (FIG. 2, 104) such that a first side (27:10-28:16; FIG. 2, 162) of the dispenser is accessible by a

pharmacy worker and such that a second side of the dispenser is accessible to the public (24:5-9; FIG. 2, 108), the dispenser having a plurality of receptacles (25:7-14; FIG. 2, 152) configured for receiving filled prescriptions and having a control portion configured for operating the dispenser (12:4-11; FIG. 1, 16; 21:20-22; FIG. 2, 116);

loading the filled prescription into one of the plurality of receptacles through the first side of the dispenser (21:5-15, 38:10-20, FIG. 6, step 3, FIG. 8, step 3);

storing information associated with the single patient sufficient to identify the single patient electronically in the controller (16:19-17:7);

storing the location of the filled prescription within the dispenser via the control portion (16:19-17:7);

associating the location of the filled prescription with the information associated with the single patient in the controller (16:19-17:7);

providing access to the second side of the dispenser so as to allow a customer to input information associated with the single patient into the controller (6:20-7:3);

dispensing the prescription to the customer once the information associated with the single patient has been entered (8:10-18).

69. A method for dispensing prescriptions comprising:

transmitting at least one prescription for medication to a pharmacist  
(19:12-17, FIG. 8, step 1);

filling the at least one prescription by preparing a container of medication  
bearing information specific to an identified patient (29:13-17; 41:10-12);

utilizing an automated prescription dispensing machine, the machine  
having a plurality of receptacles configured for receiving filled prescriptions  
comprising labeled containers of medication and having a control portion  
configured for controlling the dispensing of the filled prescriptions from the  
machine (29:12-30:6, FIG. 2, 116, 152, FIG. 8, step 3);

loading the at least one filled prescription into one of the plurality of  
receptacles (29:12-30:6);

entering the location of the at least one filled prescription, patient  
information, and prescription information into the control portion (29:12-30:6);

providing means whereby a customer may enter information (The means  
includes a patient interface (FIG. 2, 108) which may include data interface 24  
(FIG. 1) or 124 (FIG. 2), which may have a fingerprint or retinal scanner (13:3-6),  
a keyboard (22:1), or a magnetic card reader (22:5, FIG. 2, 126));

automatically verifying the prescription with the customer after the  
customer enters sufficient information to confirm the identity of a patient (44:14-  
45:22); and

dispensing at least one of the at least one filled prescriptions to the  
customer after verification of the prescription (45:9-22).



75. A method for dispensing prescription medication comprising:

receiving a plurality of written or electronic prescriptions for medication corresponding to a plurality of different patients at a pharmacy (31:7-19);

filling the plurality of prescriptions by preparing containers of medication having information specific to an identified patient thereon (29:13-17; 41:10-12);

utilizing an automated medication dispenser which is accessible to the public, the dispenser having a plurality of receptacles configured for receiving a plurality of filled prescriptions, and having a control portion for controlling the dispensing of medication from the dispenser (29:12-30:6, FIG. 2, 116, 152, FIG. 8, step 3);

loading the plurality of filled prescriptions in the plurality of receptacles (29:12-30:6);

entering the location of each of the plurality of filled prescriptions and information associated with each patient of the plurality of different patients into the control portion (29:12-30:6);

correlating the location of each of the plurality of filled prescriptions to the information entered for the corresponding patient (29:12-30:6; 34:17-35:1; 43:7-17));

receiving at least two pieces of information from a customer and verifying whether the information entered properly identifies a patient corresponding to a filled prescription which is stored in the dispenser (44:14-23); and

dispensing a filled prescription from the dispenser in response to entry of information by a customer which corresponds to that prescription and to the patient (45:1-21).

81. A method for dispensing filled prescriptions, the method comprising:

filling a prescription by preparing a container of medication with a label bearing patient information (29:13-17; 41:10-12);

loading the filled prescription into an automated prescription dispensing system disposed so as to be accessible from both sides of a pharmacy wall, one side inside the pharmacy being configured for loading prescriptions into the automated prescription dispensing system, and another side being configured for dispensing the filled prescription to the public on the opposing side of the pharmacy wall (29:12-30:6, FIG. 2, 104, 108, 116, 152, FIG. 8, step 3); and

dispensing the filled prescription to a customer outside the pharmacy wall in response to information input by a person (FIG. 2, 104, 108; 24:5-9);

wherein the method further comprises requiring multiple pieces of information associated with a patient and verifying at least one of patient information and prescription information with the person prior to dispensing the filled prescription (44:14 - 45-22).

82. A method for dispensing filled prescriptions, the method comprising:

filling a prescription by preparing a container of medication with a label bearing patient information (29:13-17; 41:10-12);

loading the filled prescription into an automated prescription dispensing system disposed so as to be accessible from both sides of a pharmacy wall, one side inside the pharmacy being configured for loading prescriptions into the automated prescription dispensing system, and another side being configured for dispensing the filled prescription to the public on the opposing side of the pharmacy wall (29:12 - 30:6, FIG. 2, 104, 108, 116, 152, FIG. 8, step 3); and

dispensing the filled prescription to a customer outside the pharmacy wall in response to information input by a person (FIG. 2, 104, 108; 24:5-9),

wherein the method comprises scanning information about the filled prescription and sending the information to a control unit (29:12 - 30:6).

95. (Previously Presented) A method for dispensing a prescription, the method comprising:

filling a prescription by preparing a container of medication having a patient's name and other prescription information thereon by pharmacy personnel (29:13-17; 41:10-12);

pharmacy personnel placing the filled prescription in a medication holding receptacle of a prescription dispensing system having a medication holding area with a plurality of medication holding receptacles (29:12 - 30:6, FIG. 2, 104, 116, 152, FIG. 8, step 3);

electronically scanning the prescription to thereby store information about the prescription in an electronic control portion of the prescription dispensing system (29:12 - 30:6);

correlating the location of the filled prescription with the information about the filled prescription (39:12-20);

dispensing the filled prescription directly to a customer after the customer inputs information correlated to at least one of the prescription and patient to verify that the customer is authorized to receive the prescription (44:14 - 45:22).

101. (Previously Presented) A method for dispensing prescription medication comprising:

transmitting a plurality of prescriptions for a plurality of patients to a pharmacy (31:7-19);

filling the plurality of prescriptions by preparing containers of medication having information specific to a patient disposed thereon (29:13-17; 41:10-12);

utilizing an automated prescription dispensing machine located in a pharmacy which is accessible to a pharmacist for loading prescriptions into the dispensing machine and accessible to the public for dispensing prescriptions from the dispensing machine, the prescription dispensing machine comprising a plurality of prescription receiving structures, a control portion, and a customer or patient interface (29:12 - 30:6, FIG. 2, 104, 108, 116, 152, FIG. 8, step 3);

entering information regarding each of the plurality of patients into the control portion, the information being sufficient to identify each of the plurality of

patients (29:12 - 30:6);

loading the plurality of prescriptions into the dispensing machine by disposing the prescriptions on or in the plurality of prescription receiving structures (29:12 -30:6, FIG. 2, 152);

correlating the location of each of the prescriptions to the identity of the patient corresponding to the prescription (29:12 - 30:6; 39:12-20);

allowing a customer to enter information associated with a filled prescription or patient into the computer controller via the customer or patient interface (44:14 - 45:22);

confirming that a prescription for the patient is loaded into the dispensing machine (8:7-9; 35:18 - 36:8);

receiving payment from the patient for the prescription (44:14 - 45:22);  
and

dispensing the prescription to the patient by moving the prescription from the prescription receiving structure and dropping the prescription into a dispensing trough separate from the prescription receiving structure (14:20 - 15:44:14 - 45:22).

103. (Previously Presented) A method for providing a prescription to a patient comprising:

transmitting the prescription to a pharmacy (31:7-19);

having a pharmacist fill the prescription by preparing container of medication having information specific to the patient (29:13-17; 41:10-12);

utilizing an automated dispenser, the dispenser being located at least partially in the pharmacy and having a plurality of prescription receiving structures for holding a plurality of prescriptions, and configured for allowing the patient to receive the prescription without interaction with the pharmacist (29:12 - 30:6, FIG. 2, 104, 108, 116, 152, FIG. 8, step 3);

having the pharmacy staff load the prescription into the dispenser by placing the prescription on or in one of the plurality of prescription receiving structures (29:12 - 30:6, FIG. 2, 152);

sensing the prescription via sensors integral to the automated dispenser to verify the location of the prescription (35:18-23);

associating the location of the prescription with the identity of the patient in a dispenser controller (29:12 - 30:6; 39:12-20);

allowing a customer to enter information into the dispenser associated with a filled prescription (44: 14 - 45:22); and

dispensing the prescription to the customer (14:20 - 15:8, FIG. 1, 40; 24:5-9, FIG. 2, 140; 44:14 - 45:22).

107. (Previously Presented) A method for dispensing prescription medication comprising:

loading a filled prescription comprising a container of medication bearing information specific to a patient into one of a plurality of receiving structures of an automated prescription dispenser, the dispenser being located in a pharmacy so as to be accessible to pharmacy personnel and to pharmacy customers (29:12 -

30:6; FIG. 2, 104, 152);

sensing the prescription with an electronic sensor to verify the location of the prescription (15:16-18; 26:13-18; 29:12 - 30:6; FIG. 2, 160, 178);

receiving, from a customer, identifying information through a control portion of the dispenser information that is sufficient to confirm the identity of the customer;

requiring the customer to enter multiple pieces of information to confirm the identity of the patient and/or prescription (44:14 - 45:22);

the dispenser verifying the prescription with the customer (44:14 - 45:22);  
and

dispensing the prescription from automated prescription dispenser to the customer after verification of the prescription (44:14 - 45: 22).

(6) GROUND OF REJECTION TO BE REVIEWED ON APPEAL

(A) Whether claims 60-80, 93 and 95-112 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Williams et al. (U.S. Pat. No. 5,597,995) in view of Schlamp (U.S. Pat. No. 5,385,265) and further in view of Liff et al. (U.S. Pat. No. 5,713,485).

(B) Whether claims 81-94 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over Williams et al. in view of Schlamp.

(7) ARGUMENT

(A) The Examiner's rejection of claims 60-80, 93 and 95-112 was improper and should be reversed.

The Final Office Action commits plain error by repeatedly failing to make out a prima facie case of obviousness. Specifically, the Final Office Action fails to identify any teaching inherent within the cited references which suggests their combination, let alone teachings which would suggest their combination in such a manner that would contain each and every element of any of the claims. Thus, the rejection is improper and should be reversed.

Additionally, the Final Office Action relies on the combination of Williams et al. (U.S. Pat. No. 5,597,995) in view of Schlamp (U.S. Pat. No. 5,385,265) and Liff et al. (U.S. Pat. No. 5,713,485) in order to reject 40 pending claims, but fails to analyze the specific claim elements and show where they are taught in the combination. Rather, the entire analysis rejecting 40 claims (with a variety of different points of novelty) provides only vague generalities and is only two pages long. In fact, the rejection only specifically references two dependent claims. Even with regard to those two claims, the Final Office Action fails to show where the actual elements of the claims are set forth in the prior art relied upon. For example, the Final Office Action fails to show where the cited art teaches:

- “utilizing an automated medication dispenser . . .” and “loading the filled prescription into one of the plurality of receptacles through the first side of the dispenser” as taught in Claim 60;
- “providing counseling regarding the prescription to the customer via the automated dispenser” as set forth in Claim 66;
- “automatically verifying the prescription with the customer after the customer enters sufficient information to confirm the identity of a patient” as claimed in Claim 69;



- “automatically billing an insurance company for at least a part of the prescription, at the time of sale” as set forth in Claim 77;
- “wherein the method further comprises requiring multiple pieces of information associated with a patient and verifying at least one of patient information and prescription information with the person prior to dispensing the filled prescription” as taught in Claim 81;
- “wherein the method comprises scanning information about the filled prescription and sending the information to a control unit” as set forth in Claim 82;
- “using a sensor to determine if a filled prescription is in a medication holding receptacle” as claimed in Claim 86;
- “dropping the filled prescription into a trough from which it can be retrieved by a customer in response to information input by a customer” as taught in Claim 91;
- “electronically scanning the prescription to thereby store information about the prescription in an electronic control portion of the prescription dispensing system” as set forth in Claim 95;
- “dispensing the prescription to the patient by moving the prescription from the prescription receiving structure and dropping the prescription into a dispensing trough separate from the prescription receiving structure” as claimed in Claim 101;
- “sensing the prescription via sensors integral to the automated dispenser to verify the location of the prescription” as claimed in Claim 103;
- “associating each of the plurality of prescriptions with the identity of the patient corresponding to each of the plurality of prescriptions” as set forth in Claim 105;

- “the dispenser verifying the prescription with the customer” as set forth in Claim 107; and
- “scanning the prescription before or during loading to enter information about the prescription into the control portion of the dispenser” as taught in Claim 110.

Many of these elements were specifically argued by Applicant as being points of novelty. By failing to specifically address the claim language, the Final Office Action has failed to demonstrate a *prima facie* case of obviousness. Additionally, it fails to make out a prima facie case of obviousness by showing why one of ordinary skill in the art would rely on the art cited, and what teachings suggest a combination of elements as set forth in the claims. The numerous failings of the Final Office Action are discussed in detail below.

#### (1) Lack of Prima Facie Case of Obviousness

The initial burden of presenting a prima facie case of obviousness rests with the examiner. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443m 1444 (Fed. Cir. 1992). It is impermissible to conclude that an invention is obvious based solely on what the examiner considers to be basic knowledge or common sense. *See In re Zurko*, 258 F.3d 1379, 1386, 59 USPQ2d 1613, 1697 (Fed. Cir. 2001). Thus, the burden is on the examiner to identify concrete evidence in the record to support his conclusion that it would have been obvious to employ the device taught in Schlamp in combination with the pharmacy of Williams and the machine of Liff et al. *See In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000). This burden can only be met by showing either “some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references.” *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988) (citations omitted).

The Final Office Action fails to identify an objective teaching in the prior art which suggests either the combination of the references, or their selective combination so as to meet each element of the claims. Rather, the Examiner asserts that a patent related to a pharmacy, a machine for holding medication in a doctor's office and a patent related to a large vending machine are analogous because they both relate to article handling. (Final Office Action page 3). The standard for combining references is not that they share some common aspect, but rather that there is some teaching which suggests their combination in order to have each element of the claims. Simply put, neither Williams nor Liff et al. provide any suggestion of using an automated dispenser for dispensing filled prescriptions directly to a patient. To the contrary, Williams teaches pharmacy staff dispensing the filled prescription to the customer. *See* Williams, Col. 10, lines 53-56. Liff et al. teaches medical staff giving the filled prescription to the patient. *See* Liff et al., Col. 1, Lines 64-66.

While Liff et al. does suggest that the machine could be used to deliver containers of medication directly to a patient, Col. 5, lines 15-25, Liff et al. would also require the patient to scan the container of medication and receive a printed label with prescription information and to print instructions for use. Col. 5, lines 26-31. One of skill in the art would appreciate that such a scenario is a disaster waiting to happen. If the patient obtained two or more containers of medication and accidentally misapplied the labels, he or she may be getting a potentially fatal overdose of one medication, and a non-therapeutic dose. Furthermore, it is usually illegal to dispense prescription drugs to a patient without the prescription information on the container or packaging.

Thus, there is no teaching in the pharmacy patents which suggest that it would be desirable for a pharmacist to fill the prescription and then use an automated prescription filling

device to dispense a filled prescription. Williams et al. and Liff et al. teach just the opposite - systems to speed up the filling of the prescription.

Likewise, there is no teaching in Schlamp that the device could be use for dispensing controlled substances, such as filled prescriptions. To the contrary, Schlamp teaches that goods are simply placed in a compartment that has been identified with a customer number and the price of the product. The customer then obtains the goods by entering an account number and/or customer number. Schlamp, Col. 5, line 47 - Col. 6, line 45. The only teaching that a vending device similar to Schlamp could be used to improve dispensing of filled prescriptions is Applicant's pending application and several applications of others which were filed years after Applicant's priority date. Thus, the rejection is improper under 35 U.S.C. § 103.

(2) The combination of Williams, Schlamp and Liff et al. has not been supported

In establishing a prima facie case of obviousness, the PTO "cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Id.* at 1600. While Applicant admits that virtually every element of a claim may be found somewhere in the prior art, this is not the test to determine whether the prior art renders the invention obvious. Rather, "[t]he test is whether the claimed invention as a whole, in light of all the teachings of the references in their entirety, would have been obvious to one of ordinary skill in the art at the time the invention was made." *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983).

In the Final Office Action, the Examiner asserts that it would have been obvious to combine Williams, Schlamp and Liff et al. because Schlamp teaches holding a merchant's goods and Williams teaches the use of a will call area. The Examiner asserts it would be obvious to use Schlamp so that medication can be placed in one side and taken from the other, but fails to

address why a person skilled in the pharmacy arts would look to Schlamp in the first place. As noted above, there must be a teaching in the art which suggests the combination – and that teaching cannot come from Applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The mere fact that Schlamp teaches a vending device is inadequate. Vending devices have existed for over a hundred years, and yet the Examiner fails to explain why a person of ordinary skill in the art did not conceive of dispensing filled prescriptions until Applicant’s invention. The very art of record in the present case demonstrates that the pharmacy industry has spent the last thirty years trying to automate prescription delivery, yet no one relied on such technology to store and dispense filled prescriptions. *See Liff et al.*, Col. 1, lines 5-58. Rather, as will be explained below, vending devices were commonly used to dispense containers of medication to the pharmacist who would then fill the prescription by printing and applying a label with patient information, use instructions, etc., and hand the filled prescription to the patient while counseling the patient on proper use of the medication.

Furthermore, the teachings of Schlamp would discourage one of skill in the pharmacy art from utilizing the system of Schlamp. In Schlamp, access to the contents of a bin is obtained by simply entering a customer account number and/or customer number and then providing payment. Col 6, lines 33-44. Schlamp does not teach or suggest a mechanism for patient counseling, for obtaining verification that the customer actually received the proper medication, for confirming that a medication was properly placed in the machine, or the ability to verify that the proper prescription is present. These issues are of significant importance in the field of pharmacy, but are likely of much less importance to the customer in Schlamp.

The Examiner has failed to explain why a person of ordinary skill in the art of dispensing medication would look to a vending machine which lacks such protections. While Schlamp may

be modified to address these issues, doing so is only obvious after one has had the benefit of Applicant's disclosure. The historical record simply reinforces this fact.

Even if one were to view Schlamp as being beneficial in the pharmacy, the Examiner has failed to identify any teaching that would suggest loading filled prescriptions into any dispensing device, let alone Schlamp. The pharmacy arts contain numerous applications in which vending machines are used to improve the prescription filling process. The Examiner, however, has failed to show any references which suggest using an automated dispensing machine to dispense a filled prescription directly to a patient.

In order to justify the rejection, the Examiner picks and chooses from aspects of the prior art, while simultaneously ignoring teachings in the reference which are inconsistent with the offered combination. For example, Liff et al. is cited as part of the combination for rejecting the claims. Liff et al., however, actually teaches away from the combination suggested by the Examiner. Liff et al. teaches a machine with a plurality of slots for placement in a doctor's office or the like. The machine is not disposed on opposing sides of a pharmacy wall. To the contrary, the access to the machine is all on the same side. Thus, loading and dispensing occur from the same side of the wall.

Each slot in Liff et al. is filled with a large number of containers of a common medication. If a patient needs a prescription, the container of medication is dispensed to the doctor or other health care worker, who then fills the prescription by printing and applying to the container a label with patient information. Col. 4, lines 54-59. The other alternative is to dispense an unlabeled medicine container to a patient and hope the patient applies the label properly. Thus, the Examiner relies on Liff et al. to claim some elements obvious, while simultaneously overlooking the underlying teaching of Liff et al. that a label must be applied to

the container of medication after it has been dispensed to achieve a filled prescription.

Likewise, Williams et al. teaches a system for improving productivity within the back-end of the pharmacy. Williams et al., however, uses conventional will call system, having pharmacy staff deliver the medication to the patient. Col. 10, lines 46-62. There is no suggestion in either Liff et al. or Williams that the prescription can be dispensed directly to a patient after being filled by a pharmacist. Thus, the combination is simply unsupported.

Additionally, the Examiner asserts that one of ordinary skill in the art would have been motivated to use Schlamp's device in Williams' pharmacy to reduce storage area and reduce the distance required for the pharmacist to reach the system. Ironically, using the Schlamp device would have the exact oppose effect. With the modification proposed by the Examiner, the Williams' pharmacy would have to have a traditional shelves for patient medications that will be picked up directly from pharmacy staff, and the automated dispenser for those prescriptions that will be picked from the dispenser. Simply put, there has been no showing that a person of ordinary skill in the art (i.e. a pharmacist) would have looked to Schlamp prior to Applicant's disclosure.

- (3) Even if the combination of Schlamp, Williams and Liff et al. were supported, the combination does not teach all of the claim elements.

The Examiner has failed to make a prima facie case of obviousness in that he has failed to show either (a) some objective teaching in the prior art that suggests combining the references, (b) knowledge generally available to one of ordinary skill in the art which would lead that individual to combine the relevant teachings of the references to achieve the invention claimed, or (c) that the combination would teach each element of the rejected claims. *See In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988).

When making a rejection under 35 U.S.C. § 103 there are three fundamental areas the Examiner is required to cover under 37 CFR § 1.106 and MPEP § 706.02. First, the rejection should set forth the differences between the claims and the prior art. Second, the proposed modification of the applied references necessary to arrive at the claimed subject matter should be set out. Third, there must be an explanation as to why such proposed modifications would be obvious. *See* MPEP 706.02(j). Furthermore, the suggestion to combine the references must come from the prior art, and not from the teachings in Applicant's disclosure. *In re Vaeck*, supra. With the above background in mind, the rejections under 35 U.S.C. § 103 will be discussed.

As discussed above, the Examiner failed to provide any teaching in the references which suggests the combination. Vending electronics, etc., is markedly different than dispensing medication which must be customized for each and every customer, by having labeling with the customer's name, the dosage amounts and frequency for taking the medication. Additionally, the dispensing of medication is strictly controlled by state law and precautions must be taken to ensure that the medication was actually delivered to the patient. Schlamp lacks any suggestions to control the dispensing of medication in such a manner.

In addition to showing a teaching to combine the references, the Examiner is required to show both that the combination contains each element of the claims **and** that the teaching would lead that individual to combine the relevant teachings of the references to achieve the claimed invention. In other words, the combination must teach each and every element of the rejected claims and suggest the combination of those elements. *See In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Rather than conducting such an analysis, the Final Office action merely engages in hindsight reconstruction, selectively picking and choosing from the prior art, while



ignoring teachings in the art which are inconsistent with the combination asserted. Several of these teaches were specifically identify, but remain unaddressed.

Even if the combination asserted by the Examiner was supported (which it is not), the rejections in the Final Office Action are improper because there has been no showing that the combination would result in a method including each element of the claims. Throughout prosecution of this case, Applicant has repeatedly identified elements in the claims which are not taught by the combination raised by the Examiner, and identified teachings in the references which teach away from the specific combination in the claims. Each office action, however, merely argues that the general combination is proper and again rejects the claims. Thus, 40 claims (including 7 independent claims) are rejected in two pages of analysis despite the substantial difference between the claims.

To the extent that the remarkably brief rejection even addresses the claim elements, it selectively picks and chooses from the prior art and amounts to hindsight reconstruction in a manner prohibited by *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Applicant respectfully submits that the Final Office Action does not make out a prima facie case of obviousness as to any of the claims. Specifically, the Final Office Action fails to show how the various cited references would be brought together to practice each and every element of the claims. Thus, the claims should be allowed.

(4) The Claims Rejected Under Schlamp, Williams and Liff et al. are Patentable.

(a) Claim 60 is patentable over the prior art

Claim 60 combines the elements of filling a prescription, loading the filled prescription into a dispenser which is accessible from two sides, storing information about the patient and dispensing the medication to a customer only after the information associated with the patient is

entered. Williams et al. teaches filling a prescription, placing the prescription in a conventional will-call area and having pharmacy staff hand the prescription to the patient when ready. Col. 10, lines 54-62. Liff et al. teaches dispensing the medication filled container, then filling the prescription by printing and applying the label with patient information. Neither patent teaches nor suggests dispensing directly to a patient a prescription which has been filled by a pharmacist, etc. Thus, there is no motivation to dispense a filled prescription by adding a vending machine (Schlamp) from some other area of art.

Schlamp does not teach or suggest use with a prescription. Furthermore, Schlamp requires only the entry of a customer number and/or an account number, rather than any information specifically tied to a patient. While the Examiner asserts it would be obvious to use the device of Schlamp in the pharmacy of Williams et al., he provides no suggestion in any of the cited art that teaches or suggest the automated dispensing of filled prescriptions. There are numerous systems which teach dispensing a container with medication and then applying a label. See e.g. Halvorson (U.S. Pat. No. 4,847,764); Liff et al. However, none of the art teaches the desirability of dispensing a prescription filled by a pharmacist - i.e. a container of medication which has already been labeled by the pharmacist for a particular patient - directly to a patient. Thus, the elements of claim 60 are not taught. As the final office action does not set forth a prima facie case of obviousness, the claim should be allowed.

(b) Claim 61 is patentable over the prior art

Claim 61 adds additional novelty. Claim 61 requires that the information regarding both the patient and the filled prescription be stored electronically in the control portion. This combination of elements is not taught in any of the prior art relied upon by the Examiner. In Williams et al., there is no automated dispensing. In Liff et al., the prescription is not filled until

after the medication container has been dispensed from the machine and a label attached thereto. In Schlamp, the merchant merely inputs the customer/account number and the price for the ordered goods. Thus, claim 61 is patentable over the prior art, as there is no teaching in the art to enter and store information about the filled prescription.

(c) Claims 62 through 65 are patentable.

Claim 62 adds the additional novelty of disposing the dispenser in a pharmacy wall. The Examiner asserts that the claim is rendered obvious because Schlamp teaches that the unit can be disposed in a wall. The Office Action, however, makes no showing why a pharmacy would elect to use a dispenser such as Schlamp. There is no motivation to consume additional pharmacy space until one appreciates the advantages of dispensing filled prescriptions through an automated dispenser. No such teaching has been shown in the cited art.

Furthermore, the Examiner's suggestion of replacing the will-call area of Williams et al. with the automated vending machine of Schlamp would not result in the dispenser being disposed in the wall, and would remove the will-call area of Williams et al., which would be necessary for prescriptions that cannot be dispensed through an automated dispenser. Claims 63 through 65 add further points of novelty and should be allowed.

(d) Claim 66 is patentable

Claim 66 requires that counseling be provided regarding the prescription via the automated dispenser. Schlamp provides no teaching regarding counseling, nor does it suggest any mechanism for doing so. In Williams et al., any counseling would be provided by the health care worker who delivers the medication. Liff et al. either suggests that the filled prescription be provided by a health care worker, or a patient being left on their own to convert medicine, labels and printouts into a filled prescription. Thus, even if combined, Schlamp, Williams and Liff et

al. do not teach each element of the claimed invention.

(e) Claim 67 is patentable.

Claim 67 is patentable because there is simply no teaching in the references which would suggest placing a filled prescription in an automated dispenser and then collecting payment when it is dispensed. While Schlamp teaches collecting payment, there is no suggestion in any of the references to use Schlamp to dispense a filled prescription.

(f) Claim 68 is patentable.

Likewise, Claim 68 adds additional novelty. The claim requires billing an insurance company at the time of sale. Contrary to the assertions by the Examiner, this is not taught by Liff et al. Specifically, Liff et al. states that it can accept third party payer cards, and that the system can “format electronic third party billings for processing by the health care provider.” Col. 4, lines 35-36 and Col. 9, lines 12-19. Clearly, if the billings will be processed by the health care provider they have not been automatically billed to the insurance company at the time of sale. Thus, claim 68 should have been allowed.

(g) Claims 69-74 are patentable.

Claim 69 includes the element of the dispensing machine verifying the prescription with the customer after the customer enters information, and that the prescription is dispensed after verification of the prescription. This element is not taught in the prior art and no explanation is given as to why the claim would be obvious. Thus, the rejection is improper both because the underlying combination is not supported and because the combination, if proper, does not teach the claimed invention. Thus, claim 69 and all claims dependant thereon should be allowed.

(h) Claims 75-76 and 78-80 are patentable.

Claim 75 requires that at least two pieces of information are received from the customer

and verified to ensure that the information identifies a patient corresponding to a filled prescription. The Final Office Action failed to demonstrate where each element of claim 75 is found in the art, along with the teachings which suggest the specific combination set forth in the claims. Thus, claim 75 and all claims dependant thereon should be allowed.

(I) Claim 77 is patentable.

Claim 77 adds the further point of novelty of automatically billing a third party at the time of sale. Liff teaches accepting a third party payer card or formatting an electronic payment request for processing by the health care provider, but fails to teach automatically billing a third party at the time of sale. Col. 4, 35-36 and Col. 9, lines 12-19. If a payment request is formatted for further processing by the health care service provider, it presumably has not been billed to the third party payer at the time of sale.

As noted in the application, one of the problems faced by pharmacies is the billing of customers. If the billing is done at the time the prescription is filled, any charges for prescriptions which are not picked up within a defined amount of time must be credited back to the insurance company. If the billing is done at the time of sale, the pharmacist or pharmacy technician must take time away from patient counseling. The present invention automatically resolves both concerns by automatically billing the third party payer at the time of sale.

(j) Claim 93 is patentable

Claim 93 is patentable over the prior art. In addition to requiring multiple pieces of information from the patient, claim 93 is patentable because Liff et al. does not teach billing a third party once the prescription has been dispensed. Rather, Liff et al. teaches formatting information for processing by the health care service provider. Thus, the elements of claim 93 are not taught in the prior art and claim 93 should be allowed.

(k) Claims 95-100 are patentable.

Claim 95 is patentable as the cited art does not teach electronically scanning the prescription and storing it in the system and correlating the information about the prescription with the location of the prescription as set forth in claim 95. The Final Office Action fails to even specifically address this element of the claim and where it is taught in the cited art. Rather the Final Office Action asserts that it would be obvious to use sensors to detect prescriptions in each of Williams “bins” and that the motivation would be to detect jammed bins and monitor inventory. (Final Office Action, page 4).<sup>1</sup> In Liff et al., the sensors (36) are used to monitor inventory (i.e. whether there are still containers of medicine A in bin (5)) and to detect jammed bins.

The cited motivation, however, appears to have no relevance to Williams et al. Williams et al. teaches automated filling machines 240, 250, 260, 270, and a conventional will-call system in which a plurality of shelves or slots (384) are provided to hold the filled prescription until they are picked up. It is unclear how these slots (384) could become jammed, or how a sensor in the slots would detect such a jam. Furthermore, a sensor would help monitor inventory if it is used in a situation in which a particular slot or bin would have a particular type of medication - similar to the bins of Liff et al. In a conventional will-call system such as Williams, however, the shelf that holds antibiotics for John Jones one minute may hold skin ointment Sally Johnson, moments later. Thus, the Examiner has shown no motivation to use sensors in Williams et al.

Furthermore, even if sensors were used in Williams et al., the Examiner has failed to show that they would be used in the manner set forth in claim 95, namely electronically scanning

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<sup>1</sup> It is unclear whether this statement was made relative claim 95 or claim 103, and thus Applicant will address the argument with respect to both claims.

the prescription to store prescription information in the electronic control portion of the prescription dispensing system and correlating the location of the filled prescription with the information about the filled prescription. Likewise, there is no such teaching in Schlamp. Thus, claim 95 and all claims depending therefrom should be allowed.

(l) Claims 101 and 102 are patentable

Claims 101 and 102 are patentable. There is simply no suggestion in the prior art to selectively pick and choose from Williams et al., Schlamp and Liff et al. to use a method in which a plurality of prescriptions are filled and stored in a machine, patient information is entered, the location of the prescriptions correlated, and the other elements of the claims. The Examiner provides only vague generalities and fails to make a prima facie case that each element in the claim is taught in the cited art in such a manner as to suggest their combination to achieve the claimed invention. Thus, the claims should be allowed.

(m) Claims 103-106 are patentable

In addition to the lack of support for the combination, even the combination suggested by the Examiner fails to teach a method which includes sensing the location of a filled prescription to verify the location of the prescription. While the Examiner asserts that it would be obvious to use the sensors of Liff et al., the sensors (36) of Liff et al. merely detect whether containers of medicine are present in a given bin and whether there is a jam. (Col. 5, lines 8-14) . The containers detected are not filled prescriptions and they do not correlate the location of a prescription with the identity of a patient. In fact, in Liff et al., there is no filled prescription until after the container of medication has been dispensed from the machine and the container labeled with patient information. Thus, there is no basis for correlating the location of a filled prescription with patient information, because Liff et al. is incapable of such.

The Examiner's assertion that it would be obvious to use such Liff et al.'s sensors in the bins of Williams (Final Office Action page 4), is not only unsupported, it would not result in the claimed invention. In fact, the Examiner also suggests that it would be obvious to replace the bins of Williams with the machine of Schlamp (Final Office Action page 3). Obviously, if the sensors are in the bins of Williams and the bins are replaced with Schlamp, the dispensing device lacks sensors. Likewise, if the device of Schlamp is placed next to the bins of Williams, the dispensing device lacks sensors, as the Examiner suggests it would be obvious to place the sensors in the bins. Furthermore, there is no teaching to place sensors in Schlamp, as the machine of Schlamp functions in a materially different way than the dispensing machine of Liff et al.

Thus, there is simply no teaching in the prior art to use any sort of a sensor to verify the location of a filled prescription. Thus, claims 103-105 are patentable. Claim 106 depends from allowable claim 61 and is also allowable.

(n) Claim 107 is patentable over the prior art.

Claim 107 is patentable, as the Examiner has failed to make a prima facie case of obviousness. Specifically, claim 107 includes sensing the prescription with an electronic sensor to verify the location of the prescription and requiring the customer to enter multiple piece of identifying information. Contrary to the Examiner's assertion, Liff et al. does not verify the location of a prescription. To the contrary, Liff et al. does not even fill the prescription until after the container of medicine has been dispensed from the machine. Likewise, neither Schlamp nor Williams teach the use of sensors to verify location of the prescription in a dispenser. Thus, there is simply no basis on which to reject claim 107.

(o) Claim 108 is patentable.



Claim 108 requires sensing the prescription within the automated dispenser to verify location. This is simply not taught in any of the prior art relied upon by the Examiner. Thus, the rejection is improper and claim 108 should be allowed.

(p) Claim 109 is patentable.

The Examiner has failed to provide any teachings in the prior art which would suggest the selective combination of elements from Schlamp, Williams and Liff et al. to achieve all of the elements of claim 109. Thus, claim 109 should be allowed.

(q) Claim 110 is patentable.

The Examiner has also failed to show where any of the prior art teaches scanning the prescription prior to loading to enter information about the prescription into the control portion. This element is completely inconsistent with Liff et al., as the prescription in Liff et al. is not filled until after the container is removed from the machine. Neither Schlamp nor Williams provide any teaching which would suggest scanning a prescription to obtain information for the controller. Thus, claim 110 is patentable.

(r) Claim 111 is patentable.

Nothing in Liff et al. teaches or suggests using a sensor to determine if a filled prescription is located in a receiving structure. To the contrary, Liff et al. teaches a system where the sensors merely indicate whether containers of medication are present in a particular bin. The container must then be dispensed to the health care provider, who prints a label with prescription information, labels the container to create a filled prescription and then hands the filled prescription to the patient, or dispensed to the patient who must apply the label, etc. This is completely inconsistent with the claimed invention. Likewise, Schlamp and Williams fail to disclose use of a sensor to determine if a filled prescription is disposed in the receiving structure

of an automated dispenser.

(s) claim 112 is patentable.

As noted above, Liff et al. does not teach the use of automatic billing. To the contrary, Liff et al. formats a bill for further processing by the health care provider. Thus, Liff et al. does not teach the elements of claim 112. Schlamp and Williams provide no suggestion to modify Liff et al. (or vice versa) to provide automatic billing to a third party at the time of sale. Thus, claim 112 is patentable.

(B) The Claims Rejected Under Williams in view of Schlamp are patentable.

(1) Claim 81 is patentable

Claim 81 is patentable over the cited prior art because the prior art does not teach each of the claim elements. For example, claim 81 requires the entry of multiple pieces of information associated with a patient (which is not taught in the cited art) and verifying at least one of the patient information and prescription information with the person prior to dispensing the filled prescription. In Schlamp there is no such teaching, as it would be unnecessary for selling fungible goods. Williams lacks such elements as it is unnecessary when the patient is delivered to the patient or customer by a health care professional. Because the prior art does not teach the claim elements, they cannot be said to render the claim obvious.

(2) Claim 82 is patentable.

Claim 82 is patentable because neither Williams nor Schlamp teach scanning information about the filled prescription and sending it to a control unit. While the Examiner provides argument why it would be obvious to combine Williams and Schlamp, no argument is provided as to where this element is found, taught or even suggested in these references. Thus, claim 82 should be allowed.

(3) Claim 83 is patentable.

Claim 83 is patentable, as none of the art teaches utilizing scanned information to determine the location of the filled prescription. Williams uses a conventional open will-call area. Schlamp does not teach or suggest such a step. Even Liff et al., which is not cited against claim 83, fails to disclose the use of scanned information for locating the prescription. Thus, the prior art neither suggests the combination, nor teaches the elements of the claim if combined.

(4) Claims 84 and 85 are patentable

Claims 84 and 85 are patentable as each depends from an allowable claim.

(5) Claim 86 is patentable

Claim 86 is patentable as neither Williams or Schlamp teaches using a sensor to determine if a filled prescription is in a holding receptacle. In fact, neither use sensors in a related manner. Thus, the combination of the art simply does not teach verifying the presence of a filled prescription in a medication holding receptacle.

(6) Claim 87 and 88 are patentable

The prior art does not teach closing a door on the side of the dispensing unit to selectively limit access, nor do they teach a plurality of doors for the same purpose.

(7) Claims 89 and 90 are patentable

Neither Schlamp nor Williams teach loading a plurality of prescriptions into the a single medication holding receptacle. Likewise, the prior art does not teach dispensing multiple prescriptions at once.

(8) Claim 91 is patentable

Claim 91 is clearly patentable over the cited art. None of the art teaches dropping a filled prescription into a trough for access by a customer after the customer inputs certain information.

Even if the combination of Williams and Schlamp were proper, the elements of claim 91 are simply not taught. Applicant has raised this lack of teaching in the prior art, but received no response in the Final Office Action. Thus, the Examiner has failed to make a prima facie case of obviousness and claim 91 should be allowed.

(9) Claim 93 is patentable

As noted above, claim 93 is patentable over Williams, Schlamp and Liff et al. because none of the references teach billing a third party payer once the prescription has been dispensed. Liff et al. teaches preparing forms for further processing by the health care provider. Schlamp is completely irrelevant, as it does not teach third party billing. Williams suggests conventional pharmacy billing. Thus, Claim 93 is allowable over Williams and Schlamp alone.

(10) Claim 94 is patentable.

Claim 94 teaches periodically removing the undispensed prescriptions. This is not taught by either Williams or Schlamp. Thus, claim 94 is allowable.

(c) The Examiner failed to give any weight to secondary indicia of nonobviousness.

The Final Office Action is also flawed because it fails to take into account the secondary considerations of nonobviousness. In *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966) and many cases since, the Courts have identified different factors which must be considered when such secondary evidence is present. These include, evidence of commercial success, fulfilling a long-felt need, and the failure of others to solve the problem and copying. *Custom Accessories, Inc. v. Jeffrey-Allan Industries*, 807 F.2d 955, 960 (Fed.Cir.1986). Secondary considerations must be considered before a decision on obviousness is reached.

*Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed.Cir.1983). Furthermore, secondary considerations may be the most revealing evidence available, *Ashland Oil, Inc., v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 306 (Fed.Cir.1985), *cert. denied*, 475 U.S. 1017, 106 S.Ct. 1201, 89 L.Ed.2d 315 (1986); *Custom Accessories, Inc.*, 807 F.2d at 960; *W.L. Gore & Associates v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed.Cir.1983), *cert. denied*, 469 U.S. 851, 105 S.Ct. 172, 83 L.Ed.2d 107 (1984), and are entitled to great weight when the evidence is strong. *Simmons Fastener Corp.*, 739 F.2d at 1576. *See also Panduit Corp. v. Dennison Manufacturing Co.*, 810 F.2d 1561, 1569 (Fed.Cir. 1987), *cert. denied*, 481 U.S. 1052, 107 S.Ct. 2187, 95 L.Ed.2d 843 (1987) (" 'In appraising an inventor's contribution to the art ... the most reliable test is to look at the situation before and after it appears' ") (quoting *Safety Car Heating & Lighting Co. v. General Electric Co.*, 155 F.2d 937, 939 (2nd Cir.1946) (L. Hand, J.)).

In the present case, there is no dispute that there is a long-felt need. The record in the present case contains numerous patents which attempt to improve the efficiency of delivering medication to patients. Williams, Liff et al., Lion (U.S. Pat. Nos. 5,838,575 and 6,330,491) and other patents which have been cited by both the Examiner and Applicant demonstrate that there is a need to improve the delivery of medication to patients. *See e.g.* U.S. Pat. Nos, 4,847,764; 5,377,864; 5,408,443; 5,713,485; 6,021,392; 6,219,587; 6,256,967; 6,352,200; and U.S. Provisional Application No. 60/210,303.

There has been substantial recognition of the load placed on pharmacists, as noted in U.S. Pat. No. 5,838,575 (Lion) Col. 1, lines 17-64. Attempts at automating portions of pharmaceutical delivery have been made for more than thirty years. Liff et al., Col. 1, lines 5-6. Despite these attempts, however, there was still a need for improvement at the time Applicant made his invention.

Much of the prescription filling art of record in this case typically falls into two general categories. One teaches methods for speeding up the back end – i.e. prescription filling – of the pharmacy. Liff et al. and Williams are prime examples of this approach to solving the need. The other common approach seeks to replace the pharmacy with an integrated filling/dispensing kiosk. Examples of such systems are discussed in U.S. Pat. Nos. 5,838,575; 6,330,491 and 6,529,801. Thus, it is clear from the volume of patents attempting to improve prescription filling and delivery that there is a long-felt need.

None of this art, however, teaches using a machine to receive and then dispense a filled prescription. Thus, there is a demonstrated long-felt need and Applicant has provided a solution to that need.

The desirability of Applicant's solution is demonstrated by those who have sought to apply Applicant's solution to the problem. Applicant filed his patent application in September 2000 and began installing prototypes of his invention. The PCT application for the invention was published on March, 14, 2002.

On August 27, 2002, Ken Rosenblum filed a continuation-in-part application to the application which issued as U.S. Patent No. 6,529,8801. Mr. Rosenblum's original application taught the desirability of providing a unit that would utilize bulk containers of medicine to fill a container with medicine, apply a label and then dispense the filled prescription to a patient without intervention by a pharmacist. In his continuation in part application, however, Mr. Rosenblum added the concept of a dispenser which received filled prescriptions from pharmacy staff. Ironically, Mr. Rosenblum has received U.S. Pat. No. 6,892,941 for the invention, despite filing his application nearly two years after the priority date of Applicant.

Mr. Rosenblum is not the only inventor to decide that it is an improvement to provide an

automated dispenser for receiving filled prescriptions from a pharmacist for later delivery to a patient. Linda Pinney et al. have filed two patent applications for dispensing units for deliver filled prescriptions. *See* U.S. Patent Appl. Nos. 10/801,321 and 10/880,269. Both applications claim back to a Provisional Application 60/484,544 filed July 1, 2003.

In 2004, Stuart Baker et al. filed U.S. Patent Application Nos. 10/830,365 and 10/927,167 which disclosed machines which pharmacy staff can load with filled prescriptions so that the filled prescriptions are dispensed directly to the customer.

The fact that the Examiner has been unable to find any patents or references which teach automated dispensing of a filled prescription prior to Applicant's priority date in September 2000 and that no fewer than five applications have been filed disclosing machines configured to dispense filled prescriptions have been filed since the public disclosure of Applicant's invention strongly suggests that Applicant's invention was nonobvious in 2000 and that it met a long-felt need in the industry.

In addition to the substantial evidence that others have adopted Applicant's approach to improve the dispensing of filled prescriptions, the Final Office Action failed to consider the evidence submitted that Applicant has received substantial unsolicited media coverage of the devices which implement the invention, and has received significant product inquiries and orders for the invention. (See Declaration of William Holmes, Appendix B, Exhibit 1). Stories about prescription dispensing machines that are loaded with filled prescriptions in accordance with the present invention have been featured on Good Morning America (Appendix B, Exhibit 2), Channel 8 News (Appendix B, Exhibit 2), CNN Live at Daybreak (Appendix B, Exhibit 3), ABC News (Appendix B, Exhibit 4), LA Times.com (Appendix B, Exhibit 5) and DRUG TOPICS (Appendix B, Exhibit 6). It should thus be appreciated that Applicant's invention represents a

revolution in pharmacy technology. The Final Office Action, however, failed to even address any of the evidence of nonobvious that was submitted. Thus, the rejection of the claims should be reversed.

(8) CLAIMS APPENDIX

A copy of claims 60-112 as currently pending is “Appendix A.”

(9) EVIDENCE APPENDIX

Attached hereto as Appendix B, are is the following evidence, which was submitted as part of Applicant’s Amendment on December 14, 2005.

Exhibit 1 - Declaration of William Holmes

Exhibit 2 - Video from Good Morning America and from Channel 8 News

Exhibit 3 - CNN Live at Daybreak

Exhibit 4 - ABC News

Exhibit 5 - LATimes.com

Exhibit 6 - DRUG TOPICS

It is requested that the evidence be entered and considered.

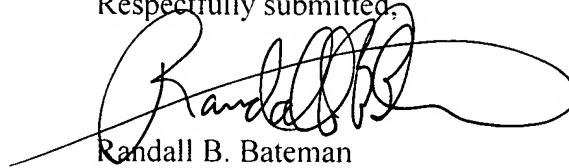
(10) RELATED PROCEEDINGS APPENDIX

There are no related proceedings.



The commissioner is hereby authorized to charge any amount owing and to credit any overpayment to Account No. 502720.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Randall B. Bateman", written over a horizontal line.

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## **APPENDIX A**

60. A method for dispensing medication comprising:

filling a prescription by placing information unique to a single patient on a container of medication;

utilizing an automated medication dispenser, the dispenser being located in a pharmacy such that a first side of the dispenser is accessible by a pharmacy worker and such that a second side of the dispenser is accessible to the public, the dispenser having a plurality of receptacles configured for receiving filled prescriptions and having a control portion configured for operating the dispenser;

loading the filled prescription into one of the plurality of receptacles through the first side of the dispenser;

storing information associated with the single patient sufficient to identify the single patient electronically in the controller;

storing the location of the filled prescription within the dispenser via the control portion;

associating the location of the filled prescription with the information associated with the single patient in the controller;

providing access to the second side of the dispenser so as to allow a customer to input information associated with the single patient into the controller;

dispensing the prescription to the customer once the information associated with the single patient has been entered.

61. The method of claim 60, wherein the method comprises:

filling a plurality of prescriptions for a plurality of patients by placing information unique to each of the patients on one or more containers of medication corresponding to the particular patient's prescription or prescriptions;

loading the plurality of filled prescriptions into the plurality of receptacles, and storing electronically via a control portion information regarding the filled prescriptions;

storing electronically, via the control portion, information corresponding to the plurality of patients and sufficient to identify each of the plurality of patients;

storing the locations within the dispenser of each of the plurality of filled prescriptions in the control portion;

associating the locations of each of the plurality of filled prescriptions with the information corresponding to the particular patient which corresponds to the particular prescription in the control portion;

providing public access to the second side of the dispenser so as to allow a customer to input information associated with a patient into the controller;

dispensing to the customer the filled prescription or prescriptions corresponding to a patient once information sufficient to identify the patient has been entered.

62. The method of claim 60, wherein the method further comprises selecting a medication dispenser which is disposed in a pharmacy wall.

63. The method of claim 60, wherein the first side of the medication dispenser is disposed opposite the second side of the dispenser.

64. The method of claim 60, wherein the second side of the dispenser has an opening configured for selectively allowing a customer to retrieve at least one prescription.

65. The method of claim 60, wherein the method further comprises opening one of a plurality of doors to provide access to the filled prescription.

66. The method of claim 60, wherein the method further comprises providing counseling regarding the prescription to the customer via the automated dispenser.

67. The method of claim 60, wherein the method further comprises collecting payment from the customer for the prescription.

68. The method of claim 60, wherein the method further comprises automatically billing an insurance provider for the prescription at the time of sale.

69. A method for dispensing prescriptions comprising:

- transmitting at least one prescription for medication to a pharmacist;
- filling the at least one prescription by preparing a container of medication bearing information specific to an identified patient;
- utilizing an automated prescription dispensing machine, the machine having a plurality of receptacles configured for receiving filled prescriptions comprising labeled containers of medication and having a control portion configured for controlling the dispensing of the filled prescriptions from the machine;

loading the at least one filled prescription into one of the plurality of receptacles;  
entering the location of the at least one filled prescription, patient information,  
and prescription information into the control portion;  
providing means whereby a customer may enter information;  
automatically verifying the prescription with the customer after the customer  
enters sufficient information to confirm the identity of a patient; and  
dispensing at least one of the at least one filled prescriptions to the customer after  
verification of the prescription.

70. The method of claim 69, wherein the method further comprises:  
transmitting a plurality of prescriptions for medication to a pharmacist;  
filling a plurality of prescriptions;  
loading each of the plurality of filled prescriptions into receptacles of the plurality  
of receptacles;  
entering for each of the plurality of filled prescriptions the location of the filled  
prescription and patient information; and  
dispensing to a customer one or more of the plurality of filled prescriptions  
corresponding to a single patient in response to the entry of information sufficient to identify the  
patient into the dispenser.

71. The method of claim 69, wherein the method further comprises charging the  
customer for the dispensed filled prescription.

72. The method of claim 69, wherein the dispensing machine is located in a pharmacy wall.

73. The method of claim 69, wherein the method further comprises having pharmacy staff load the filled prescription into the dispensing machine.

74. The method of claim 69, wherein the method further comprises allowing customers to receive prescriptions from the dispensing machine after the pharmacy is closed.

75. A method for dispensing prescription medication comprising:

- receiving a plurality of written or electronic prescriptions for medication corresponding to a plurality of different patients at a pharmacy;
- filling the plurality of prescriptions by preparing containers of medication having information specific to an identified patient thereon;
- utilizing an automated medication dispenser which is accessible to the public, the dispenser having a plurality of receptacles configured for receiving a plurality of filled prescriptions, and having a control portion for controlling the dispensing of medication from the dispenser;
- loading the plurality of filled prescriptions in the plurality of receptacles;
- entering the location of each of the plurality of filled prescriptions and information associated with each patient of the plurality of different patients into the control portion;
- correlating the location of each of the plurality of filled prescriptions to the

information entered for the corresponding patient;

receiving at least two pieces of information from a customer and verifying whether the information entered properly identifies a patient corresponding to a filled prescription which is stored in the dispenser; and

dispensing a filled prescription from the dispenser in response to entry of information by a customer which corresponds to that prescription and to the patient.

76. The method of claim 75, wherein then method further comprises charging the customer for at least a part of the cost of the prescription.

77. The method of claim 75, wherein the method further comprises automatically billing an insurance company for at least a part of the prescription, at the time of sale.

78. The method of claim 75, wherein method comprises dispensing the filled prescription via an opening so that it is accessible by the customer.

79. The method of claim 75, wherein the method further comprises providing a plurality of doors in communication with the plurality of receptacles and selectively actuating one of the plurality of doors after the patient enters sufficient information to identify the patient.

80. The method of claim 75, wherein the method further comprises selectively releasing from one of the plurality of receptacles a filled prescription corresponding to a customer after the customer enters information sufficient to identify and provide authorization of a patient so as to

allow the customer to retrieve the prescription.

81. A method for dispensing filled prescriptions, the method comprising:

filling a prescription by preparing a container of medication with a label bearing patient information;

loading the filled prescription into an automated prescription dispensing system disposed so as to be accessible from both sides of a pharmacy wall, one side inside the pharmacy being configured for loading prescriptions into the automated prescription dispensing system, and another side being configured for dispensing the filled prescription to the public on the opposing side of the pharmacy wall; and

dispensing the filled prescription to a customer outside the pharmacy wall in response to information input by a person;

wherein the method further comprises requiring multiple pieces of information associated with a patient and verifying at least one of patient information and prescription information with the person prior to dispensing the filled prescription.

82. A method for dispensing filled prescriptions, the method comprising:

filling a prescription by preparing a container of medication with a label bearing patient information;

loading the filled prescription into an automated prescription dispensing system disposed so as to be accessible from both sides of a pharmacy wall, one side inside the pharmacy being configured for loading prescriptions into the automated prescription dispensing system, and another side being configured for dispensing the filled prescription to the public on the opposing



side of the pharmacy wall; and

dispensing the filled prescription to a customer outside the pharmacy wall in response to information input by a person;

wherein the method comprises scanning information about the filled prescription and sending the information to a control unit.

83. The method according to claim 82, wherein the method further comprises utilizing the scanned information to determine the location of the filled prescription within the automated prescription dispensing system.

84. The method according to claim 81, wherein the method comprises utilizing information input by the customer into a control unit and dispensing the filled prescription to the person when adequate information has been received to verify that the customer has authorization to pick-up the filled prescription.

85. The method according to claim 81, wherein the method comprises placing the filled prescription in a medication holding receptacle and correlating which medication holding receptacle holds the filled prescription with information correlated with the patient.

86. The method according to claim 85, wherein the method comprises using a sensor to determine if a filled prescription is in a medication holding receptacle.

87. The method according to claim 81, wherein the method comprises selectively closing at

least one door on the side of the automated prescription dispensing system in which filled prescriptions are loaded to selectively limit access to the filled prescriptions.

88. The method according to claim 87, wherein the method comprises providing a plurality of doors disposed adjacent medication holding receptacles and where the doors selectively inhibit dispensing filled prescriptions from the medication holding receptacles.

89. The method according to claim 81, wherein the method comprises disposing a plurality of filled prescriptions in a single medication holding receptacle.

90. The method according to claim 89, wherein the method comprises dispensing the plurality of filled prescriptions in response to information input by a customer and associated with a patient.

91. The method according to claim 81, wherein the method comprises removing at least one filled prescription from at least one medication holding receptacle and dropping the filled prescription into a trough from which it can be retrieved by a customer in response to information input by a customer.

92. The method according to claim 81, wherein the method further comprises charging the customer for the filled prescription prior to dispensing the filled prescription.

93. The method according to claim 81, wherein the method further comprises billing a third

party for at least a portion of the cost of a prescription once the prescription has been dispensed.

94. The method according to claim 81, wherein a plurality of filled prescriptions are disposed in the automated prescription dispensing system, and wherein the filled prescriptions which have not been dispensed are periodically removed from the automated prescription dispensing system by pharmacy personnel.

95. A method for dispensing a prescription, the method comprising:

filling a prescription by preparing a container of medication having a patient's name and other prescription information thereon by pharmacy personnel;

pharmacy personnel placing the filled prescription in a medication holding receptacle of a prescription dispensing system having a medication holding area with a plurality of medication holding receptacles;

electronically scanning the prescription to thereby store information about the prescription in an electronic control portion of the prescription dispensing system;

correlating the location of the filled prescription with the information about the filled prescription;

dispensing the filled prescription directly to a customer after the customer inputs information correlated to at least one of the prescription and patient to verify that the customer is authorized to receive the prescription.

96. The method according to claim 95, wherein the method comprises charging the customer prior to dispensing the filled prescription.

97. The method according to claim 95, wherein the method comprises disposing the prescription dispensing system so that a loading side is disposed on a side of a pharmacy wall accessible to pharmacy personnel, and a dispensing side is disposed where it is accessible to customers.

98. The method according to claim 95, wherein the method comprises loading filled prescriptions into the prescription dispensing system on a side opposite the side accessible to customers.

99. The method according to claim 95, wherein the method further comprises releasing the prescription from the receptacle so as to allow the customer to retrieve the prescription.

100. The method according to claim 99, wherein the prescription dispensing system further comprises a plurality of dispensing doors corresponding to the plurality of receptacles, and wherein the method further comprises selectively actuating one of the plurality of dispensing doors to dispense a filled prescription in response to input by a customer.

101. A method for dispensing prescription medication comprising:

- transmitting a plurality of prescriptions for a plurality of patients to a pharmacy;
- filling the plurality of prescriptions by preparing containers of medication having information specific to a patient disposed thereon;
- utilizing an automated prescription dispensing machine located in a pharmacy which is accessible to a pharmacist for loading prescriptions into the dispensing machine and accessible to the public for dispensing prescriptions from the dispensing machine, the prescription

dispensing machine comprising a plurality of prescription receiving structures, a control portion, and a customer or patient interface;

entering information regarding each of the plurality of patients into the control portion, the information being sufficient to identify each of the plurality of patients;

loading the plurality of prescriptions into the dispensing machine by disposing the prescriptions on or in the plurality of prescription receiving structures;

correlating the location of each of the prescriptions to the identity of the patient corresponding to the prescription;

allowing a customer to enter information associated with a filled prescription or patient into the computer controller via the customer or patient interface;

confirming that a prescription for the patient is loaded into the dispensing machine;

receiving payment from the patient for the prescription; and

dispensing the prescription to the patient by moving the prescription from the prescription receiving structure and dropping the prescription into a dispensing trough separate from the prescription receiving structure.

102. The method of claim 101, wherein the method further comprises selecting a dispensing machine having a plurality of dispensing doors associated with the plurality of prescription receiving structures, and wherein the method further comprises dispensing a prescription to a patient by selectively actuating one of the plurality of dispensing doors.

103. A method for providing a prescription to a patient comprising:

transmitting the prescription to a pharmacy;

having a pharmacist fill the prescription by preparing container of medication having information specific to the patient;

utilizing an automated dispenser, the dispenser being located at least partially in the pharmacy and having a plurality of prescription receiving structures for holding a plurality of prescriptions, and configured for allowing the patient to receive the prescription without interaction with the pharmacist;

having the pharmacy staff load the prescription into the dispenser by placing the prescription on or in one of the plurality of prescription receiving structures;

sensing the prescription via sensors integral to the automated dispenser to verify the location of the prescription;

associating the location of the prescription with the identity of the patient in a dispenser controller;

allowing a customer to enter information into the dispenser associated with a filled prescription; and

dispensing the prescription to the customer.

104. The method of claim 103, wherein the dispenser is located in the wall of the pharmacy.

105. The method of claim 103, wherein the method further comprises:

having the pharmacist fill a plurality of prescriptions for a plurality of patients;

loading the plurality of prescriptions into the dispenser by placing the plurality of prescriptions on or in the plurality of prescription receiving structures;

associating each of the plurality of prescriptions with the identity of the patient  
corresponding to each of the plurality of prescriptions;

dispensing one of the plurality of prescriptions in response to a customer entering  
sufficient information into the dispenser to identify a patient.

106. The method of claim 61, wherein the method further comprises dispensing a plurality of  
filled prescriptions to a plurality of different customers.

107. A method for dispensing prescription medication comprising:

loading a filled prescription comprising a container of medication bearing information  
specific to a patient into one of a plurality of receiving structures of an automated prescription  
dispenser, the dispenser being located in a pharmacy so as to be accessible to pharmacy  
personnel and to pharmacy customers;

sensing the prescription with an electronic sensor to verify the location of the  
prescription;

receiving, from a customer, identifying information through a control portion of the  
dispenser information that is sufficient to confirm the identity of the customer;

requiring the customer to enter multiple pieces of information to confirm the identity of  
the patient and/or prescription;

the dispenser verifying the prescription with the customer; and

dispensing the prescription from automated prescription dispenser to the customer after  
verification of the prescription.

108. The method of claim 107, wherein sensing the prescription with an electronic sensor comprises automatically sensing the prescription within the automated prescription dispenser to verify location.

109. The method of claim 107, wherein the method further comprises moving the prescription from the receiving structure to a separate dispensing structure to dispense the prescription to the customer.

110. The method of claim 107, wherein sensing the prescription with an electronic sensor comprises scanning the prescription before or during loading to enter information about the prescription into the control portion of the dispenser.

111. The method of claim 107, wherein sensing the prescription with an electronic sensor comprises utilizing the sensor to determine if a filled prescription is in a receiving structure.

112. The method of claim 107, wherein the method further comprises the dispenser automatically billing a third party for at least a portion of the cost of the prescription.



## **APPENDIX B**

Exhibit 1 - Declaration of William Holmes

Exhibit 2 - Video from Good Morning America and from Channel 8 News

Exhibit 3 - CNN Live at Daybreak

Exhibit 4 - ABC News

Exhibit 5 - LATimes.com

Exhibit 6 - DRUG TOPICS

**IN THE UNITED STATE PATENT AND TRADEMARK OFFICE**

In re application of: **Walter M. Bain**  
Serial Nunber: **10/755,849**  
Filed: **January 12, 2004**  
Art Unit: **3653**  
Examiner: **Jeffrey A. Shapiro**  
For: **Automated Prescription Dispensing System and  
Method of Use**  
Old Attorney Docket: **1311.APT.CI**  
New Attorney Docket: **1311.DDN.CN**

Mail Stop Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313,1450

I hereby certify that this correspondence is being deposited with the United States Postal Service via First Class Mail, addressed to:  
Mail Stop Non-Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313,1450 on *[Signature]* 12-14-05

**DECLARATION OF WILLIAM HOLMES**

I, William Holmes, hereby declare

1. I am over the age of 18 and competent to make this declaration.
2. I am the President of Distributed Delivery Networks, the owner by assignment of the 10/755,849 application, and have been personally involved in the pharmaceutical delivery business since 1994.

In Re Application of Walter M. Bain  
Serial Number: 10/755,849

3. Since we have started testing our automated delivery system, we have received substantial unsolicited media coverage, including numerous television interviews, which focus on the ability of the system to speed up the delivery of medication from the pharmacist to the patient. Copies of television reports and articles are attached hereto.

4. We have also received substantial commercial interest in our automated delivery system. We have had several large pharmacy chains that have asked to test one of our units and several have moved into the contract negotiation stage already.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated this 13<sup>TH</sup> day of December, 2005.

William F. Holmes  
William Holmes

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## CNN LIVE AT DAYBREAK

West Bank Pullout; Prescription ATM; Left Behind?; Serial Bomber

Aired August 23, 2005 - 06:30 ET

THIS IS A RUSH TRANSCRIPT. THIS COPY MAY NOT BE IN ITS FINAL FORM AND MAY BE UPDATED.

CAROL COSTELLO, CNN ANCHOR: To the Israeli pullout from four settlements in the West Bank now. A sign atop the last building holding protesters in Sanur says a curse upon any of those who remove us from our home. Guy Raz is watching developments there. Here joins us live now.

Hello -- Guy.

GUY RAZ, CNN CORRESPONDENT: Hi, Carol.

Police and soldiers appear to be waiting it out at the moment, trying to negotiate their entry into this community center right behind us, hoping that those inside will leave on their own.

Now, if we could just take a look at the top of that building you can see a few demonstrators up there. We believe there are several dozen demonstrators up there, most of those hard line settlers, opponents of the government's plan to withdraw Jewish settlers from these four northern West Bank settlements.

Now, earlier in the day police stormed a synagogue in this community and managed to enter that synagogue rapidly and remove all of the people inside of that synagogue.

Right now, what they appear to be doing is waiting it out for this last holding, this community center. (folds, essentially once this center is evacuated, we can say with a fair amount of confidence that the process that began now just less than a week ago will be over -- Carol.

COSTELLO: Guy Raz reporting live from the West Bank this morning.

Well, you knew it was only a matter of time before automation put even the corner drug dealers out of next, would you get your prescriptions from an ATM -- or an APM, we should say? Is it a good idea? We're coming right back.

But first, here's a look at what else is making news this Tuesday.

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### Road Runner High Speed Internet

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(COMMERCIAL BREAK)

COSTELLO: It's time now for the market report. Mixed trading in the international markets this morning closes up 20 points, Britain's FTSE is trading down 16, the German DAX down about 34.

It looks like Islam will play a major role in the new Iraqi constitution. So what will that mean for women?

Soledad O'Brien joins us now for a look at what's coming up on "AMERICAN MORNING."

Good morning.

SOLEDAD O'BRIEN, CNN ANCHOR: Hey, Carol, good morning to you.

Yes, actually lots of questions remain in this new constitution or this draft constitution. It's on hold until differences can be ironed out. But women's rights advocates already are worried about the draft that will women actually lose some of the rights that they gained under Saddam Hussein's rule? We're going to take a closer look at that this morning.

Also, Carol, our special back-to-school series continues. That's hard to say. Today, are you setting your alarm with a full day of homework and sports and then other activities? Are some children seriously over-scheduled? You know, that can cause anxiety, depression in little kids. We're going to have some tips to help you find a healthy balance.

That's all ahead on "AMERICAN MORNING" coming up at the top of the hour -- Carol.

COSTELLO: All right, thank you, Soledad.

Continuing our business news now. You can get food, drinks, tickets and even your money out of an ATM about prescription drugs? That may be coming to a store near you.

And the man hoping to put it there, Bill Holmes, president of Distributed Delivery Networks. He joins us now. Diego to talk about the ATM-like drug dispensers.

Good morning, Bill.

BILL HOLMES, DISTRIBUTED DELIVERY NETWORKS: Good morning, Carol.

COSTELLO: Thanks for waking up so early.

HOLMES: My pleasure.

COSTELLO: So, tell us about these machines.

HOLMES: Well, the idea is to take the place of a shortage in pharmacists and step in and try to fill the gap in automation where people just aren't available.

COSTELLO: So, how exactly do they work?

HOLMES: Well, it's a simple four-step process. First, you call a prescription in, a refill prescription in to drop it by the pharmacy. The pharmacist then fills the prescription in the usual manner, loads the prescription into the APM dispensing machine. The customer approaches the machine, just like an ATM, uses a password card to make the payment. And then the machine dispenses the prescription and verifies the prescription.

COSTELLO: So, you would call your purchase in to the actual pharmacist. He would fill your prescription and just put it in that machine instead of handing it over to you.

HOLMES: Exactly.

COSTELLO: I don't know. Are there are safeguards built in? Because, you know, there are mistakes

HOLMES: Well, the technology isn't brand new. The credit goes to someone named Walter Bain (ph) from Utah, who is a 40-year veteran in pharmacy. And over three years where this technology has been deployed in that area, there has been zero instances of the wrong package going to the consumer. For example, bar code technology to verify accuracy just prior to delivering the package to the customer, we have implemented that to prevent that kind of a mismatch.

COSTELLO: You know, some people have to get a lot of prescriptions filled all at once. How many dr out of there at the same time?

HOLMES: Any drug that's verified by the pharmacist and does not require any consultation in states 1 of a restriction on the use of these machines could be dispensed in a group or individually if the patie

COSTELLO: Of course, the big concern here is you don't get that one on one with your pharmacist. Y or her questions like, you know, should I take this medication with alcohol, or to make sure that this n right medication.

HOLMES: Yes, the machine asks you when you're in the process of picking up your prescription if yo pharmacist, and provisions are made for that to take place. The machines are immediately adjacent t so there's really no reason why you can't talk to a pharmacist at that point.

COSTELLO: Well, what if the pharmacy is closed though?

HOLMES: Then we would only use the machine if there was a telephone nearby, where that prescrip vended, so the pharmacist would have access -- would be accessible by the patient. Or if the patient example, that they would like a consultation, we would not vend in that case and refer the person to c next day.

COSTELLO: OK. I know there are machines up and running in California. Where else?

HOLMES: Utah, California. Our most recent installation is in the Kmart store in Penn Station in downt

COSTELLO: I didn't even know about that one. So, do you think that this will soon spread countrywid

HOLMES: If people find the machines convenient and if accuracy is improved, as we believe it will be used by retailers who are interested in providing convenience and safety for their customers.

COSTELLO: Bill Holmes, thank you so much for joining us this morning. We appreciate it.

HOLMES: My pleasure, Carol.

COSTELLO: Your news, money, weather and sports. It's 6:39 Eastern. Here's what's all new this mor

Eric Rudolph has apologized in court for the 1996 Atlanta Olympics bombing. But he didn't say he wa other bombings he committed, including one at a clinic where abortions are performed. Rudolph was yesterday in Atlanta to life in prison.

In money news, the NFL is looking for the official beer sponsor of the 2006 season. And, boy, is it wo bucks. "USA Today" reporting two brewers in negotiations are Anheuser-Busch and Coors. Coors ha deal right now, which it is hoping to renew.

In culture, conservative radio host Michael Graham has been fired after he refused to apologize for c terrorist organization. Graham's broadcast in late July drew protests from the Council on American Is

In sports, she says she dreamed of it all of her life, and now Maria Sharapova is number one in world That means she'll probably be the top seed at the U.S. Open, which starts here in New York on Monc

(WEATHER REPORT)

COSTELLO: From the classroom to the courtroom. Connecticut has become the first state to sue the administration over the No Child Left Behind Act. The federal education law is supposed to raise sch Connecticut wants to know who is going to pay for it.

Mark Davis from our affiliate WTNH has details.

(BEGIN VIDEOTAPE)

MARK DAVIS, CNN AFFILIATE WTNH REPORTER (voice over): Over the next few weeks, 570,000 school kids will go back to public schools. But teachers and administrators have been having fits abo testing to grades 3, 5 and 7, in addition to the tests that have been conducted in grades, 4, 6, 8 and 1 Connecticut for years.

COMM. BETTY STERNBERG, CONN. DEPT. OF EDUCATION: The additional tests as imposed by of NCLB have questionable merit.

DAVIS: The additional testing mandated by the federal No Child Left Behind Act championed by Pres Bush is, according to school administrators, the general assembly and this lawsuit, an illegally-imposed mandate, forcing the state and cities and towns to spend money they don't have.

DON WILLIAMS, CONNECTICUT STATE SENATE: It is as great as \$40 million in unfunded mandate and as much as \$400 million in unfunded mandates to our cities and towns.

DAVIS: Educators say requiring school systems to get the test scores higher will only result in teaching tests.

H. KAYE GRIFFIN, MADISON SCHOOL SUPT.: In many cases, that can only be done with direct intervention, very costly, is one of the major issues that we all face.

DAVIS: The lawsuit seeks to either stop the forced testing or get the federal government to pay for it.

RICHARD BLUMENTHAL, CONNECTICUT ATTORNEY GENERAL: Literally, it's give up the illegal revenue and use the money. One or the other.

DAVIS: Governor Jodi Rell, who originally opposed the idea of a lawsuit against the federal government, is now reluctantly going along. Her education commissioner has been rejected several times in attempts to give the state some sort of waiver.

GOV. JODI RELL (R), CONNECTICUT: And while I would have preferred, as I said, to work through the normal mechanism, I believe if he wants to pursue, he certainly should be able to do so.

(END VIDEOTAPE)

COSTELLO: Mark Davis from our affiliate WTNH.

The death toll continues to rise, and the president's approval rating continues to fall. Up next, an in-depth look at the war is going on and the perception of how the war is going.

Plus, we'll tell you what else will be making news today.

But first, say happy birthday.

(COMMERCIAL BREAK)

COSTELLO: And welcome back. It is 6:46 Eastern. Here is what will be making news today.

It could save you some money -- gas money in the future. This morning, Transportation Secretary Norman Mineta announces a big overhaul of fuel economy standards. The plan would require SUVs, light trucks and better gas mileage. CNN will bring you Mineta's news conference in Atlanta live. Our coverage begins at 7:00 Eastern.

And finally, Pat Robertson is talking tough. The Christian broadcaster says the U.S. should assassinate leftist president, Hugo Chavez. Robertson says Chavez is trying to spread communism, and he says that over a huge oil reserve makes him a threat.

How is this for strange bedfellows? The presidential adviser and Jimi Hendrix? They're both coming up on "AMERICAN MORNING."

Miles, Jimi Hendrix couldn't possibly be coming up on "AMERICAN MORNING."

MILES O'BRIEN, CNN ANCHOR: No, we definitely don't have Jimi Hendrix. But that would be an even bigger surprise. Yes.

COSTELLO: It would. I'd be tuned in.

M. O'BRIEN: All of the exclusives are here on CNN. No, we will be joined by the presidential counsel. Although a draft of the new Iraqi constitution has been submitted, a lot of people would say it isn't so clear what the White House thinks about all of this. A bit of a setback, but some could look at it as progress.

depends on who you ask, of course.

And then we'll talk to the author behind the new Jimi Hendrix biography. "Room Full of Mirrors," it is c interesting details about Jimi Hendrix.

You know, I knew a lot about his music, Carol, but not so much about him. How about you?

COSTELLO: I know. And some fascinating details are coming out.

M. O'BRIEN: A voracious appetite, you might say. And I'll just leave it at that.

COSTELLO: For many things.

M. O'BRIEN: We'll fill in the details later. Yes, Carol.

COSTELLO: For the best thing in life.

M. O'BRIEN: We'll see you here soon.

COSTELLO: All right, thanks, Miles.

M. O'BRIEN: All right.

COSTELLO: When we come back, more headlines and a look at your travel forecast. You're watching a Tuesday.

(COMMERCIAL BREAK)

COSTELLO: Eric Robert Rudolph, once a defiant terrorist, is now an apologetic prisoner. The convict tells victims and their families he's sorry for their pain. He made those remarks during a court appear

Paula Zahn reports on the homegrown terrorist.

(BEGIN VIDEOTAPE)

PAULA ZAHN, CNN ANCHOR (voice-over): January 16, 1997, two bombs explode at a women's clinic in a suburb, an abortion clinic. Seven people are injured. February 21, 1997, another bombing attack on a church in Atlanta injures four people.

UNIDENTIFIED MALE: A bomb explosion, the New Women's Abortion Clinic.

ZAHN: January 29, 1998, a bomb explodes outside a Birmingham, Alabama, abortion clinic. A security guard is seriously injured. A suspect is spotted. A witness catches his license plate. It's traced back to the home of Eric Robert Rudolph.

While searching Rudolph's trailer home in North Carolina, police make a startling discovery. Bomb-m the police say is linked to the 1996 Atlanta Olympic terrorist bombing that killed one person and injured more than 100.

But why did Eric Rudolph choose these targets? He's not saying, but someone who knows him well says he is an extremist filled with hate.

(on camera): Who does Eric Rudolph hate and why?

DEBORAH RUDOLPH FORMER SISTER-IN-LAW OF ERIC RUDOLPH: The government would be a lot better off if they just let him go.

ZAHN: And why?

RUDOLPH: They control everything. And I think that he -- you know, I think he has issues with control.

ZAHN (voice-over): Deborah Rudolph was married to Eric's brother, Joel, for six years. She watched him harden into a man with very strong opinions.

RUDOLPH: A lot of people say that he's a racist. I wouldn't classify him as a racist, knowing him personally. He believes that every -- each race should be true to themselves. He believes that the history of the white race, and that the other races in the Bible, you know are, are just -- he would call them just people.



ZAHN: Eric was raised by his mother, a former nun who eventually turned the family to darker beliefs. There were always mercenary magazines laying around the house, philosophy books, newspapers, and newspapers, like "The Lightning Bolt" or "The Thunderbolt," different kind of papers like that. I would be laying around when we would go to the mountains.

ZAHN (on camera): Who bought those?

RUDOLPH: I would assume that it was something that, you know, the family subscribed to.

ZAHN (voice-over): After Eric's father was diagnosed with cancer, the family's attitudes towards the go to hate. Mrs. Rudolph wanted to treat her husband with an illegal substance called laetrile.

RUDOLPH: They thought it was a natural way to cure or slow down cancer, made from apricot pits. I'm a self-sufficient family. And I think that that really was the topping on the cake. His mother wanted to treat laetrile. They wouldn't allow it. And, you know, she was very outspoken about it. And the children, of course, that.

ZAHN (voice-over): So, the family hunkered down in the North Carolina mountains, generating their own water filtering their own water. Eric loved to smoke marijuana and watch movies, but not TV. Deborah says she was controlled by Jews.

RUDOLPH: He would actually watch the TV and watch the credits roll. See, see, Steinbergs, this and that would -- you know, he would just go on this. He would become very animated and go off on a rant, about, you know, all these Jews that are in the media and on the news, so they control the information people are receiving.

ZAHN: As Eric Rudolph got older, he turned into a man willing to use terror to make his point.

CNN senior investigative reporter Henry Schuster has written a new book about Eric Rudolph.

HENRY SCHUSTER, CNN PRODUCER: Friends who saw Eric up to the time of the Olympic Games increasingly, he would sit in his house with the curtains drawn. He would be ranting against the government, he would be watching TV and going into these terrific rages. He was increasingly paranoid about surveillance by the government.

ZAHN: So, why did Eric Rudolph choose the Olympics and abortion clinics as his targets? Deborah Finkelstein knows.

RUDOLPH: And I think it goes back to a race thing, again, back to this idea that the majority of abortions in this country are performed on white women. But yet black women, Hispanic women are allowed to have them and the government is going to support them. So, I think that was the issue with that. The Olympics, I think of all of these people coming from all different countries and cultures and colors and races and religions together in one place.

ZAHN: But Deborah Rudolph also says she saw something in her former brother-in-law that perhaps she never saw: an intelligence that was wasted.

RUDOLPH: I've always said that he was either going to be famous for something or infamous for something. He could have been a great leader of people. He could have been a great leader of men. That's how smart he was.

(END VIDEOTAPE)

COSTELLO: CNN's Paula Zahn.

Eric Robert Rudolph did not apologize for the bombings that targeted two abortion clinics and a gay restaurant.

"Now in the News."

A West Bank showdown this morning. With Gaza emptied, Israeli forces are using some force to evacuate West Bank settlements. Police broke down a barricade at a synagogue in the Sanur settlement and forced it to open.

President Bush taking a vacation within his vacation. He's spending two days at a resort in Idaho. He flew to his ranch yesterday for a pro-Iraq war speech at the V.F.W. Convention in Salt Lake City. After that, he'll be back in the White House.

Iraq's draft constitution is showing signs of progress. That's what Iraq's prime minister said this morning. He carried here on DAYBREAK within the last hour, he also admits more work has to be done. Lawmakers are still debating the draft.

voting on the draft to iron out some sticking points.

To the forecast center now and Chad. And before you give your travel forecast, we might as well give

CHAD MYERS, CNN METEOROLOGIST: We'll give away a mug. We can't ask questions today, because questions actually were covered up by that developing news story. So, that's OK. We'll certainly give tomorrow.

Here are the winner from yesterday. Who authenticated the Saddam Hussein jailhouse letter? And the International Committee of the Red Cross. And who is protesting the name of the South Carolina that is PETA.

And the winner from California. What are you doing awake? Cheryl Abbate from Palm Springs, California. DAYBREAK coffee mug today.

(WEATHER REPORT) COSTELLO: From the Time Warner center in New York, I'm Carol Costello at Myers. "AMERICAN MORNING" starts right now.

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## San Diego Pharmacy Uses Vending Machines to Dispense Prescription Refills



**June 22, 2005**— It seems you can get almost everything out of a vending machine, from soft drinks and sandwiches to umbrellas and sewing kits.

Soon you may even be able to get prescription medicine from a vending machine.

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At one drug store in San Diego, pharmacists dispense nearly 1,600 prescriptions a day. The high volume prompted owner Max Atiya to add a drug-dispensing kiosk to his store.

He says customers are buying into this new way of doing business.

"They like the fact that they don't have to deal with anyone," Atiya said. "They go to a machine and they basically dispense their medication."

First-time prescriptions still go through a pharmacist, but the automated pharmacy machine can be used to streamline the refill process.

Bill Homes of the Distributed Delivery Networks Corp. created the machine.

"People who would benefit from the machine are people who need to get in and out without consultation," Homes said.

Customers are still welcome to consult a pharmacist at any time and are encouraged to ask questions, but some in the industry worry that the machines could lead to the misuse of medicine.

"Anything that limits or diminishes the amount of face time between the pharmacist and the patient contributes to that problem," said David Breslow of the California Pharmacists Association.

Steve Fazziola, pharmacy manager, is confident with the technology.

"This machine can do as good a job as I allow it to do," Fazziola said. "And it won't get tired or make mistakes unless we mess up."

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# APPENDIX B

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MEDICINE

## Enter your PIN, get a prescription

■ Automated dispensers look and work like ATMs. They're convenient, but some pharmacists fear the loss of interaction.

By Shari Roan, Times Staff Writer

The lines at most pharmacies have gotten so frustratingly long in recent years that some people may want a Valium by the time they reach the counter.

But in this day of self-serve gas pumps and airline ticket dispensers, a solution could be at hand. Two companies have begun to install automated drug-dispensing machines, which look and operate like ATMs, in a few California stores. If customers take to the process, the machines may become increasingly commonplace.

### ADVERTISEMENT

To get their medication, consumers simply enter identifying information on a touch screen and swipe a credit card to pay for the prescription (there is no service fee). The medication — already bagged — slides down a chute. For now, the automated machines can dispense only refills, by order of the California State Board of Pharmacy.

"It's well-recognized that there is a shortage of pharmacists and the whole system is being taxed," says Bill Holmes, president and chief executive of Distributed Delivery Networks Corp., the San Marcos maker of one automated system. "But wherever there is a labor shortage, there is an automation solution."

Few consumers would disagree the lines to pick up medications have grown. A dramatic upswing in drug prescriptions in the past decade along with a shortage of pharmacists has contributed to the gridlock. And, although more people today have prescription drug insurance, questions about coverage and co-pays can slow the pace of the pick-up line — as have recent laws requiring pharmacists to offer consultations to patients receiving new prescriptions.

Pharmacies too have felt the pressures, hence their willingness to test the automated drug dispensers.

The state's first automated dispensers were recently installed in stores in the San Diego area.

Distributed Delivery Networks has a machine at White Cross Drug Store in San Diego and will open another at a Kmart in Manhattan, N.Y., this summer. A competing company, Del Mar-based Asteres Inc., has installed its machine, called ScriptCenter, at a Longs drugstore in Del Mar and will soon add machines at Longs stores in San Diego and Walnut Creek. A Vons in San Diego will also carry a ScriptCenter later this year, as will a supermarket pharmacy in Reston, Va.

Asteres founder Linda Pinney says the idea of an automated drug dispenser occurred to her while waiting at her local pharmacy to pick up her monthly medication for attention-deficit

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hyperactivity disorder, a condition that can make concentration and extended patience difficult.

"I thought, 'This is crazy; I have ADHD,'" says Pinney, who has a background working in healthcare automation technology. "I was determined that this was a problem that needed to be solved."

Pharmacy experts agree that long waits are a problem. But they say it's too early to know how helpful automated drug dispensers may be.

California Board of Pharmacy regulations do not specifically allow dispensing through automated systems, but stores carrying the machines have been granted waivers to test the technology, says Patricia Harris, executive officer of the Board of Pharmacy. (Mail-order drug delivery is covered by different regulations.) If the machines are successful, the board may vote to alter rules to permit their use.

"Long lines are a reality in many stores," says Harris. "There are peak hours when it's really difficult for patients, and it may be more convenient to use one of these delivery systems."

The machines, which can hold hundreds of prescriptions, may prove to be of greatest value to consumers who want to pick up their prescriptions after the pharmacy has closed. In many chain drug and grocery stores, store hours are longer than the pharmacy hours.

"Many grocery stores are open 24 hours but the pharmacy closes at 7," says Pinney. "Consumers are frustrated with that."

Although pharmacists still fill the prescriptions and load the bags into the machine, automated dispensing may ease their workloads too, says Holmes.

But cutting out the human element worries some pharmacists, who have lobbied hard in recent years to increase their responsibilities for advising and educating consumers. In an April letter to the Board of Pharmacy, the California Pharmacists Assn. said the automated machines would reduce the opportunity for pharmacists and patients to interact. For example, consumers would not have the opportunity to ask questions about drug interactions or how to best use the medication.

"Convenience is not always the best thing," says John A. Cronin, senior vice president of the California Pharmacists Assn. "What concerns us is the use of this kind of technology would tend to decrease the interaction between the pharmacist and the consumer."

Cronin says his association has suggested that stores installing the technology submit a plan to the State Board of Pharmacy detailing how the machine could improve patient care.

"There is a place for these machines," he says. "We're not going to be able to suppress technological advances like this. But there needs to be a thought process about what the total impact will be on the consumer."

Pinney points out that the machines will ask consumers if they want a consultation with a pharmacist. If the answer is yes, the consumer can step into a special line (if the pharmacy is open) to speak to the pharmacist at the counter.

The machines potentially could be configured with telephones or video teleconference screens for counseling by an off-site pharmacist. And they could provide consumers with a telephone number to call a pharmacist later.

The technology will not replace pharmacists, says Pinney. "What we are is a pharmacy clerk. We are absolutely not a pharmacist."

Automated dispensing machines may even reduce the risk of some prescription errors, such as when the wrong prescription is handed to a patient, Holmes says. The machines will have several layers of security, such as requiring consumers to establish a user ID and password.

"Prescriptions going to consumers is like money going to consumers," Pinney says. "The margin for error is zero."

## TECHNOLOGY

### Vending machine automates refills via swipe of card

**P**atients will soon be able to bypass long lines at the pharmacy counter by grabbing their refill prescriptions from a secure vending machine, according to the San Diego company that developed the automation technology.

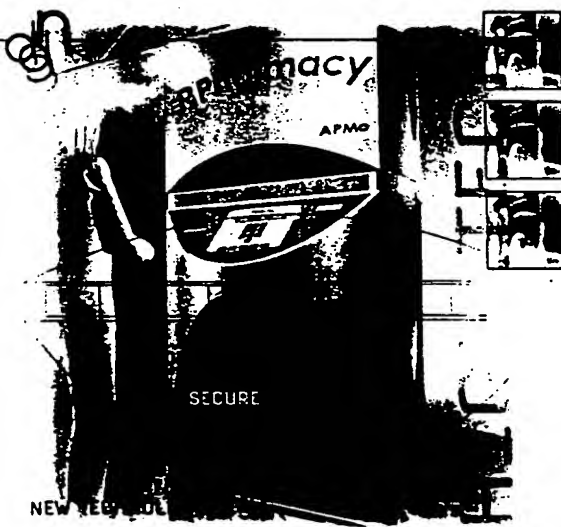
The Automated Product Machine (APM™) allows patients to identify themselves, pay for their medications with cash or a credit card, request counseling, and pick up their refills previously deposited in the vending machine by pharmacy staffers. Distributed Delivery Networks Corp. (ddn) recently unveiled the vending machine at the National Association of Chain Drug Stores Marketplace Conference in San Diego.

"The APM™ is a friendly kiosk, like an ATM or boarding pass machine at the airport," said William Holmes, ddn president. "People are very accustomed to using these types of machines and waiting in line is very frustrating. Retail drugstore chains are getting competition from the Web, mail order, big box chains, and grocery stores, so the largest driving force for our technology will be customer service. And there's also a very large pharmacist shortage. We're trying to help retail chains retain their customers through a better shopping experience and environment."

To use the APM, the customer swipes a credit card and punches in a four-digit PIN or enters the refill Rx number and his or her date of birth. Once the patient's identity has been confirmed, the screen shows all the prescriptions ready for pickup. The patient selects one or all of the Rx's, swipes a credit card or inserts cash to pay for the refill, picks up a receipt, and signs an electronic sig-

nature capture device. A small door opens on the APM, and the patient retrieves the bagged prescription.

"We also make sure the patients get the information and counseling they need," said Holmes. "They are asked whether they want a consultation. If they touch the button, the pharmacist is informed that they need service. And each package has a unique bar code that is read when it's put into the machine and again



prior to vending. The door won't open if the bar codes don't match."

Mindful that retail floor space is at a premium, the ddn designers kept the APM footprint to a minimum. Even though it occupies a space of only 2 ft. by 4 ft., the machine can store more than 1,000 small prescription packages or about 500 parcels in a more typical mix of sizes. The machine can be freestanding or built into the pharmacy wall, allowing access to the front of the unit by customers and to the rear by pharmacy personnel refilling the unit.

An APM is priced between \$45,000 and \$65,000, depending on

the bells and whistles the buyer wants. The units can be leased or purchased outright. "The return on investment is less than a year," added Holmes, who previously worked for the pharmacy automation firms Pyxis and Omnicell.

The first APMs will be installed in the pharmacy area under the direct supervision of the R.Ph. The company believes that, depending on regulatory reaction to the technology, vending machines could be placed in other locations or remain accessible when no pharmacist is physically present.

"Telepharmacy already exists," Holmes said. "We believe that there will be pressure to have it available after hours to provide the same quality and functionality as telepharmacy. I was on the phone recently with the pharmacy director of a small combo chain who thinks APM could be the answer to his prayers. A very ill patient had arrived after one of his pharmacies had closed. Because there was no pharmacist, the manager couldn't get the medication or retrieve the prescription. Our machine offers a way to serve that customer."

Moving the vending machines away from direct supervision by an on-site pharmacist will require regulatory approval from state boards of pharmacy. But instead of going to the boards itself, ddn is looking to partner with a drugstore chain that will drive the regulatory approval process. "We're very early in partnering with people in deploying the technology, so there are certain concerns about what we might do to satisfy the regulators," Holmes said. "The only way the technology will ever become widely accepted and deployed is if we can demonstrate absolute accuracy."

For more information, go to [www.ddncorp.com](http://www.ddncorp.com), telephone (760) 471-3994, or e-mail [wholmes@ddncorp.com](mailto:wholmes@ddncorp.com).

**Carol Ukens**

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